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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,194	02/02/2004	Douglas Hovey	029318-1001	3657
31049 7590 08/07/2008 Elan Drug Delivery, Inc. c/o Foley & Lardner 3000 K Street, N.W. Suite 500 Washington, DC 20007-5109				
EXAMINER				
GEORGE, KONATA M				
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
08/07/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/768,194

**Applicant(s)**

HOVEY ET AL.

**Examiner**

KONATA M. GEORGE

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17, 19-24, 27-44, 47-61, 64-67 and 69-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19-24, 27-44, 47-61, 64-67 and 69-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are pending in this application.

#### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson et al. (US 2002/0065256 A1).

Applicants claim a fluticasone composition comprising particles of fluticasone having a particles size of less than 900 nm and at least one surface stabilizer.

#### ***Determination of the scope and content of the prior art (MPEP §2141.01)***

Karlsson et al. disclose a process for sterilization of a powdered form of a glucocorticosteroid wherein the glucocorticosteroids are used in the treatment of allergic and/or inflammatory conditions of the nose or lungs (abstract). ¶ [0016] teach examples of the glucocorticosteroid used in the composition i.e. fluticasone (e.g. as propionate). ¶ [0017] teach the particle size as less than 10 microns. ¶ [0031] teach the use of the

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composition. ¶ [0033] teaches the use of pharmaceutically acceptable additives. ¶ [0035] teach suitable surfactants that can be employed in the composition, mention being made to Tyloxapol™ and polyoxyethylene alkyl ethers. ¶ [0036] teach the concentration of the surfactant at about 0.002 to 2% w/w. ¶ [0042] teach the percentage of particles having a specific particle size. ¶ [0044] teach that a suspension containing the active agent and additional ingredients can be produced by sterile filtration. The several examples teach the active agent in concentrations as claimed by applicant.

***Ascertainment of the difference between the prior art and the claims  
(MPEP §2141.02)***

Karlsson et al. do not teach specific examples using fluticasone as claimed by applicant.

***Finding of prima facie obviousness Rational and Motivation  
(MPEP §2142-2143)***

It is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the cited glucocorticosteroids in the instant invention. As paragraph [0016] teaches examples of glucocorticosteroids one of ordinary skill could substitute any one of the glucocorticosteroids listed (i.e. fluticasone) to achieve the same desired results of treating allergic and/or inflammatory condition of the nose or lungs (e.g. chronic obstructive pulmonary disease, asthma, etc.). Applicant has amended the claims to

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recite that the particles are small enough to pass through a 0.2 micron filter. Although the prior art does not teach exact size of the particle, it is the position of the examiner that since the particle size can be less than 1 micron ¶ [0017] the prior art reads on the claimed invention. Applicant would need to show why their particle size is preferred over that of the prior art.

### ***Response to Arguments***

Applicant's arguments filed May 7, 2008 have been fully considered but they are not persuasive.

Applicant argues that the method claims (39-44, 47-61, 64-67 and 69-81) recite that the entirety of the dispersion passes through a 0.2 micron filter. It is the position of the examiner that the particles of Karlsson et al. can be passed through a 0.2 micron filter as claimed. As disclosed in ¶ [0017], the particle size can be in an ultra fine form less than 1 micron. It is the position of the examiner that this recitation allows one of ordinary skill in the art to formulate the particle size very small.

Applicant argues that by not giving the claim element "sterilized by filtration through a 0.2 micron filter" patentable weight, this line of argument is inconsistent with the examiner's restriction requirement. The examiner disagrees. The restriction was to a composition and a sterile composition. The sterile composition recited the process of sterile filtering, however, it is still drawn to a sterile composition. Where claims are directed to a composition, the manner by which the individual components are made is not a patentable distinction if the resulting composition is the same as taught in the prior

art. Claims 17, 19-24 and 27-43 are directed to a composition and not a method of making the composition.

### ***Conclusion***

Claims 17, 19-24, 27-44, 47-61, 64-67 and 69-81 remain rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George  
Patent Examiner  
Art Unit 1616

/Johann R. Richter/  
Supervisory Patent Examiner, Art Unit 1616